UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

In Re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation

CARA A. BALDYGA and RALPH C. ACKROYD,

Plaintiffs,

v.

DEPUY ORTHOPAEDICS, INC., and JOHNSON & JOHNSON,

Defendants.

_____/

Assigned to:
Honorable Judge Ed Kinkeade

MDL No.: 3:11-MD-2244

COMPLAINT AND JURY DEMAND

Civil Case No.:

Plaintiffs, CARA A. BALDYGA and RALPH C. ACKROYD, by and through undersigned counsel, sue Defendants, DEPUY ORTHOPAEDICS, INC. and JOHNSON & JOHNSON, and for their Complaint allege, upon information and belief and based on the investigation to date of their counsel, as follows:

NATURE OF THE ACTION

1. Defendants manufactured the Pinnacle Hip Implant Device ("Pinnacle Device"). DePuy launched the Pinnacle Acetabular Cup System in 2001. The Pinnacle Device was designed, developed, and sold for human hip joints damaged or diseased due to fracture, osteoarthritis, rheumatoid arthritis, and avascular necrosis. The Pinnacle Device is designed to be fastened to human bone with surgical screws. The Pinnacle Device was designed and sold to provide pain relief and consistent and smooth range of motion. Defendants marketed the Pinnacle Devices as having significant advantages over other hip devices and hip replacement

systems. Defendants marketed and described the Pinnacle Device as "[u]niquely designed to meet the demands of active patients like you – and help reduce pain" and advertised it with pictures of a young woman trying on sneakers in an athletic shoe store. Defendants advertised the Pinnacle Device as superior devices featuring TrueGlide technology, allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion."

2. Defendants also advertised and sold the Pinnacle Device as the best surgical option that "[r]ecreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

3. On information and belief Plaintiffs allege that Defendants sold approximately 150,000 Pinnacle Devices. Defendants have stated in promotional materials that "99.9% of Pinnacle Hip components are still in use today."

4. On information and belief, Plaintiffs allege that over 1,300 adverse reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failures or complications of the Pinnacle Devices.

5. On information and belief, Plaintiffs allege that Defendants are aware that Pinnacle Devices may result in metallosis, biologic toxicity, and high failure rate. Plaintiffs further allege that the Pinnacle Devices result in unsafe release of toxic metal ions into hip implant recipients' tissue and bloodstream. Plaintiffs further allege that Defendants are aware that metal particles from Pinnacle Devices results in metallosis, tissue death, bone erosion, and development of tumors.

6. On information and belief, Plaintiffs allege that particulate debris from the Pinnacle Devices causes severe inflammation, severe pain, tissue and bone loss, and other related diseases.

7. Plaintiffs further allege that Defendants are aware that certain Pinnacle Device recipients have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

JURISDICTION AND VENUE

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiffs exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal place of business in states other than the state in which the named Plaintiffs reside.

9. Venue of this case is appropriate in the United States District Court for the Middle District of Florida. Plaintiffs state that, but for the order permitting direct filing into the Northern District of Texas pursuant to Case Management Order #1, Plaintiffs would have filed in the United States District Court for the Middle District of Florida. Therefore, Plaintiffs respectfully request that at the time of transfer of this action back to the trial court for further proceedings that this case be transferred to the above referenced District Court.

PARTIES

10. Plaintiffs, CARA A. BALDYGA and RALPH C. ACKROYD, are natural persons and citizens of the County of Pinellas, State of Florida.

11. Defendant DEPUY ORTHOPAEDICS, INC. ("DePuy") is an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DePuy is a resident and citizen of Indiana.

12. At all times material hereto, Defendant DePuy (hereinafter referred to as "Defendant") developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Pinnacle Device, either directly or indirectly, to members of the general public throughout the United States.

13. Upon information and belief, at all relevant times, Defendant was present and doing business in the State of Ohio and in the Middle District of Florida.

14. At all relevant times, Defendant transacted, solicited, and conducted business in the State of Florida and derived substantial revenue from such business.

15. At all relevant times, Defendant expected or should have expected that its act would have consequences within the United States, and in the Middle District of Florida in particular.

16. Defendant JOHNSON & JOHNSON ("J&J") is a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant J&J is a resident and citizen of New Jersey.

17. At all times material hereto, Defendant J&J, as the parent company of Defendant DePuy developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Pinnacle Device, either directly or indirectly, to members of the general public throughout the United States.

18. Upon information and belief, at all relevant times, Defendant J&J, as the parent company of Defendant DePuy, was present and doing business in the State of Florida and in the Middle District of Florida in particular.

19. At all relevant times, Defendant J&J, as the parent company of Defendant DePuy, transacted, solicited, and conducted business in the State of Florida and derived substantial revenue from such business.

20. At all relevant times, Defendant J&J, as the parent company of Defendant DePuy, expected or should have expected that its acts would have consequences within the United States, and in the Middle District of Florida in particular.

FACTUAL ALLEGATIONS

21. Defendants' defective device was placed into the stream of interstate commerce and was implanted in Plaintiff CARA A. BALDYGA on or about February 17, 2015.

22. As a direct and proximate result of Defendants placing the product into the stream of commerce, Plaintiff CARA A. BALDYGA has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, lost wages, and other related damages.

23. All of the injuries and complications suffered by Plaintiff CARA A. BALDYGA were caused by the defective design, warnings, construction and unreasonably dangerous character of the Pinnacle Device that was implanted in her. Had Defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the Pinnacle Device, Plaintiff CARA A. BALDYGA would not have consented to the Pinnacle Device being used in her total hip arthroplasty.

24. Plaintiff CARA A. BALDYGA was unaware of any causal link between the injuries she has suffered and any wrongdoing on the part of Defendants due to the faulty and

defective nature of the Pinnacle Device, due in part to the failures of Defendants to properly warn her and her physicians about the Pinnacle Device's defective and faulty nature.

25. As a direct and proximate result of Defendants placing the product into the stream of commerce, Plaintiff CARA A. BALDYGA's injuries consist of constant pain, and instability of the left hip.

26. The Pinnacle Device was developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), fracture, and other degenerative conditions. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

27. The Pinnacle Device is made up of four components: the metal femoral stem is inserted inside the femur bone, the metal femoral head (or ball) connects to the top of the stem and then makes contact with a liner that is attached to the interior portion of the metal acetabulum cup (socket). The acetabulum cup is comprised of titanium metal on its outer shell. Either a plastic, ceramic, or cobalt-chromium metal liner is then placed on the inside of the acetabulum cup. The metal femoral head rotates within the plastic, ceramic, or metal liner, depending on which liner the surgeon selects based on the patient's needs. The cobalt-chromium metal liner is branded by Defendants as the "Ultamet." The Pinnacle Device with an Ultamet liner is a "metal-on-metal" device due to the fact that both articulating surfaces – the femoral head (ball) and acetabulum liner (socket) – are comprised of cobalt-chromium metal.

28. The Pinnacle Device is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health or pose potentially unreasonable risks to patients.

29. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Device, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

30. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operations; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

31. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probably benefit to health from the use of the device against ay probably risk of injury or illness from such use.

32. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is known

as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least ninety (90) days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

33. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, the Pinnacle Device metal-on-metal total hip replacement system was certified to be sold on the basis of Defendants' claim that, under section 510(k) of the MDA, it was "substantially equivalent" to another older metal-on-metal hip implant device that Defendants sold and implanted prior to the enactment of the MDA in 1976.

34. As such, under the 510(k) process, Defendants were able to market the Pinnacle Device with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

35. Had Defendants conducted clinical trials of the Pinnacle Device before it was first released on the market in the early 2000's, they would have discovered at that time what they ultimately learned in and around 2007 – that the Pinnacle Device results in a high percentage of patients developing metallosis, biologic toxicity and an early and high failure rate due to the release of metal particles in the patient's surrounding tissue when the cobalt-chromium metal formal head rotates within the cobalt-chromium metal acetabular liner.

36. In other words, implantation of the Pinnacle Device results in the nearly immediate systemic release of high levels of toxic metal cobalt-chromium ions into every hip implant patient's tissue and bloodstream. This is because cobalt-chromium metal particles are released by friction from the metal femoral head rotating within the metal liner. The particles

that accumulate in the patient's tissue surrounding the implant giving rise to metallosis, pseudotumors, or other conditions.

37. The formation of metallosis, pseudotumors, and infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and a lack of mobility.

38. The problems with the Pinnacle Device are similar to the issues that gave rise to Defendants' recall of the ASR Device. Like the Pinnacle Device, the ASR is also prone to early failure, and causes metallosis and cobalt toxicity resulting in serious health problems and the need for subsequent revision surgery. As a result, in August 2010, Defendants, in acknowledging the high failure rate of the ASR, recalled more than 93,000 ASRs worldwide. It is anticipated that Defendants will at some point recall Pinnacle Devices for the same reasons.

39. Upon information and belief, Plaintiffs allege that the FDA has received more than 1,300 adverse reports regarding problems associated with or attributed to the Pinnacle Device.

40. Upon information and belief, Plaintiffs allege that many recipients of the Pinnacle Device are suffering from elevated levels of chromium and cobalt. Plaintiffs further allege on information and belief that Defendants are aware that certain recipients of the Pinnacle Device have significantly elevated levels of chromium and cobalt in amounts many times higher than acceptable or recommended safety levels.

41. A number of governmental regulatory agencies have recognized the problems that are caused by metal-on-metal implants such as the ASR and Pinnacle Device. For instance, The Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of

soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

42. Similarly, the Alaska Department of Health recently issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

43. Despite the public knowledge to the contrary, Defendants continue to misrepresent the Pinnacle Device as a high-quality, safe and effective hip replacement product in their marketing and promotional materials. This is despite the fact that Defendants have known for years that the Pinnacle Device poses a danger to patients who have it implanted.

44. As a result, Defendants continue to sell the Pinnacle Device to doctors who implant them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from metallosis, pseudotumors, and biologic toxicity, among other complications. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems caused by the defective device.

FEDERAL REQUIREMENTS

45. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

46. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 351.

47. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer or a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. *See* 21 U.S.C. § 360(i).

48. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and that facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device conform to current good manufacturing proactive, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. *See* 21 U.S.C. § 360j(f).

49. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to FDA within thirty (30) days after the manufacturer becomes aware that a device

may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See* 21 C.F.R. § 803.50.

50. Pursuant to federal regulation, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. *See* 21 C.F.R. § 803.52.

51. Pursuant to federal regulation, manufacturers must report to FDA within five (5) business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. *See* 21 C.F.R. § 803.53.

52. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or

distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 C.F.R. § 806.

53. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. *See* 21 C.F.R. § 820.

54. The regulations requiring conformance to good manufacturing practices are set forth in 21 C.F.R. § 820 *et seq*. As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing process employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

55. Pursuant to 21 C.F.R. § 820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351).

56. Pursuant to 21 C.F.R. § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizations structure, responsibilities, procedures, processes, and resources for implementing quality management. *See* 21 C.F.R. § 820.3(v).

57. Pursuant to 21 C.F.R. § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

58. Pursuant to 21 C.F.R. § 820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

59. Pursuant to 21 C.F.R. § 820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

60. Pursuant to 21 C.F.R. § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

61. Pursuant to 21 C.F.R. § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

62. Pursuant to 21 C.F.R. § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

63. Pursuant to 21 C.F.R. § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

64. Pursuant to 21 C.F.R. § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

65. Pursuant to 21 C.F.R. § 820.70(a), each manufacturer shall develop, conduct, control and monitor production process to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

a. Documented instructions, standard operating procedures (SOPs), and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified standards or codes;

d. The approval of processes and process equipment; and

e. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

66. Pursuant to 21 C.F.R. § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure.

67. Pursuant to 21 C.F.R. § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

68. Pursuant to 21 C.F.R. § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

69. Pursuant to 21 C.F.R. § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.

70. Pursuant to 21 C.F.R. § 820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

71. Pursuant to 21 C.F.R. § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.

72. Pursuant to 21 C.F.R. § 820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results.

73. Pursuant to 21 C.F.R. § 820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. *See* 21 C.F.R. § 820.3(z)(1).

74. Pursuant to 21 C.F.R. § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

75. Pursuant to 21 C.F.R. § 820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

76. Pursuant to 21 C.F.R. § 820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problem,

b. Investigating the cause of nonconformities relating to product, processes and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

g. Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

DEFENDANTS' PINNACLE ACETABULAR SYSTEM IS A 510(K) APPROVED MEDICAL DEVICE

77. Defendants submitted a § 510(k) premarket notification and obtained marketing approval for its Pinnacle Device from the FDA under Section 510(k) of the Act. *See* 21 U.S.C. § 360 *et seq*.

78. Under the § 510(k) approval process, the FDA determined the Defendants' Pinnacle Device was "substantially equivalent" to devices that have been reclassified in accordance with the provisions of the Act and did not require FDA approval of a pre-market approval application (PMA).

79. Upon information and belief, Defendants' Pinnacle Device is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

80. Upon information and belief, Defendants' Pinnacle Device is misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

81. Upon information and belief, Defendants' Pinnacle Device is adulterated pursuant to 21 U.S.C. § 351 because Defendants failed to establish and maintain CGMP for its Pinnacle Device in accordance with 21 C.F.R. § 820 *et seq.*, as set forth above.

82. Upon information and belief, Defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for its Pinnacle Device.

83. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' Pinnacle Device was defective and failed, resulting in injuries to the Plaintiff.

84. If Defendants had complied with the federal requirements regarding CGMP, Defendants' Pinnacle Device would have been manufactured properly such that it would not have resulted in injuries to the Plaintiff.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE AND NEGLIGENCE PER SE)

85. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

86. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of the Pinnacle Device into the stream of commerce, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects.

87. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of the Pinnacle Device into the interstate commerce in that Defendants knew or should have known that using the Pinnacle Device created a high risk of unreasonable and dangerous side effects, including but not limited to severe pain and suffering, the need for additional surgery to repair, remove and/or replace the Pinnacle Device, as well as other severe and permanent health consequences.

88. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating,and/or designing the Pinnacle Device without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating,and/or designing the Pinnacle Device without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not the aforesaid Pinnacle Device was safe for use; in that Defendants herein knew or should have known that the Pinnacle Device was unsafe and unfit for use by reason of the dangers to its users;

(d) Selling the Pinnacle Device without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and/or the FDA of the dangers of the Pinnacle Device;

(f) Negligently failing to recall their dangerous and defective Pinnacle Devices at the earliest date that it became known that said systems were, in fact, dangerous and defective;

(g) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with and use the Pinnacle Device;

(h) Failing to test the Pinnacle Device and/or failing to adequately, sufficiently and properly test the Pinnacle Device;

(i) Negligently advertising and recommending the use of the aforesaid Pinnacle Device without sufficient knowledge as to its dangerous propensities;

(j) Negligently representing that the Pinnacle Device was safe for use for its intended purpose, when, in fact, it was unsafe;

(k) Negligently representing that the Pinnacle Device had equivalent safety and efficacy as other, non-defective total hip replacement systems;

(l) Negligently designing the Pinnacle Device in a manner which was dangerous to its users;

(m) Negligently manufacturing the Pinnacle Device in a manner which was dangerous to its users;

(n) Negligently producing the Pinnacle Device in a manner which was dangerous to its users;

(o) Negligently assembling the Pinnacle Device in a manner which was dangerous to its users; and

(p) Concealing information concerning tests, and/or reports, and/or studies from the Plaintiff and her physicians, hospitals, and/or the FDA in knowing that the Pinnacle Device was unsafe, dangerous, and/or non-conforming with accepted industry standards;

(q) Improperly concealing information from and/or misrepresenting information to the Plaintiff, healthcare professionals, hospitals and/or the FDA, concerning the severity of risks and dangers of the Pinnacle Device;

(r) Failing to properly warn and instruct regarding the increased frequency and severity of adverse events occurring with the Pinnacle Device; and

(s) Failing to provide reasonable assurance with respect to the safety and effectiveness of the Pinnacle Device.

89. Defendants violated statutes, rules and ordinates concerning the manufacturing, marketing, and/or testing of their product.

90. Defendants under-reported, underestimated and downplayed the serious dangers of the Pinnacle Device.

91. Defendants were negligent in the designing, researching, supplying, manufacture, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Pinnacle Device in that they:

(a) Failed to use due care in designing and manufacturing the Pinnacle Device so as to avoid the aforementioned risks to individuals when the Pinnacle Device was used in total hip replacement surgeries;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse risks and side effects associated with the use of the Pinnacle Device;

(c) Failed to accompany their product with proper warnings regarding all possible adverse risks and side effects concerning the failure and/or malfunction of the Pinnacle Device;

(d) Failed to warn Plaintiff and her healthcare professionals, hospitals and/or the FDA of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(e) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Pinnacle Device;

(f) Failed to warn Plaintiff and her healthcare professionals, hospitals and/or the FDA prior to actively encouraging the sale of the Pinnacle Device, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

(g) Were otherwise careless or negligent.

92. Defendants knew or should have known that consumers such as the Plaintiff CARA A. BALDYGA would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

93. Defendants' actions, by violating statutes, ordinances and/or rules and regulations, constituted negligence per se.

94. Defendants' negligence was the proximate cause of Plaintiff CARA A. BALDYGA's injuries, harm, and economic loss which she suffered and/or will continue to suffer.

95. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA was and/or still is caused to suffer and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, and/or the need for additional surgery to repair, remove and/or replace the Pinnacle Device, as well as other severe and permanent health consequences.

96. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

97. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY)

98. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

99. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed the Pinnacle Device as hereinabove described and the Plaintiff CARA A. BALDYGA was a recipient of said product.

100. That the Pinnacle Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

101. At those times, the Pinnacle Device was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff CARA A. BALDYGA herein.

102. The Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the Pinnacle Device.

103. The Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

104. At all times herein mentioned, the Pinnacle Device was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

105. Defendants knew or should have known that at all times herein mentioned, the Pinnacle Device was in a defective condition, and was inherently dangerous and unsafe.

106. At the time of the Plaintiff CARA A. BALDYGA's receipt and/or use of the Pinnacle Device, the Pinnacle Device was being used for the purposes and in a manner normally intended, namely as a total hip replacement system.

107. Defendants, with this knowledge, voluntarily designed the Pinnacle Device in a dangerous condition for use by the public, and in particular the Plaintiff CARA A. BALDYGA and/or her healthcare professionals.

108. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

109. Defendants created a product unreasonably dangerous for its normal, intended use.

110. The Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that said Pinnacle Device left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

111. The Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Pinnacle Device was manufactured.

112. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the

health of consumers and to the Plaintiff CARA A. BALDYGA in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff CARA A. BALDYGA.

113. The Plaintiff CARA A. BALDYGA could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

114. The Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions because the manufacturer knew or should have known that the product created a risk of unreasonable, dangerous side effects, including but not limited to severe pain and suffering, and the need for additional surgery to repair, remove and/or replace the Pinnacle Device, as well as other severe and permanent health consequences, and the Defendants failed to adequately warn of said risk.

115. The Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

116. The Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, after the manufacturer knew or should have known of the unreasonable, dangerous side effects, including but not limited to severe pain and suffering, and the need for additional surgery to repair, remove and/or replace the Pinnacle Device, as well as other severe and permanent health consequences, and Defendants failed to provide adequate warnings to users or consumers of the product, and continued to promote the product.

117. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff CARA A. BALDYGA for the manufacturing, marketing, promoting, distribution, and selling of a defective product, the Pinnacle Device.

118. Defendants' defective design, manufacturing defect, and inadequate warnings of the Pinnacle Device were acts that amount to willful, wanton, and/or reckless conduct by Defendants. .

119. That said defects in Defendants' Pinnacle Device were a substantial factor in causing Plaintiff CARA A. BALDYGA's injuries.

120. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA was and/or still is caused to suffer and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, the need for additional surgery to repair, remove and/or replace the Pinnacle Device, as well as other severe and permanent health consequences.

121. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff CARA A. BALDYGA is informed and believes and further alleges that Plaintiff CARA A. BALDYGA will in the future be required to obtain further medical and/or hospital care, attention, and services.

122. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(DESIGN DEFECT)

123. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

124. At all times herein mentioned, Defendants engaged in the business of developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, retailing, supplying, and/or selling the Pinnacle Device.

125. Upon information and belief, the Pinnacle Device was defective at the time of its manufacture and marketing.

126. The Pinnacle Device was defectively designed and/or manufactured so as to be unreasonably dangerous to consumers, including the Plaintiff CARA A. BALDYGA.

127. The Pinnacle Device was marketed by Defendants for use in Pinnacle Device surgeries for consumers, and Plaintiff CARA A. BALDYGA became a consumer and relied upon the safety of the defendants' product.

128. At all times herein mentioned, the Pinnacle Device and the sales and promotional materials, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, retailed, supplied, and/or sold by defendants were defective including one or more of the following particulars:

a) Pinnacle Devices contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Plaintiff CARA A. BALDYGA to risks which exceeded the benefits of the device;

b) Pinnacle Devices were defective in design and formulation, making use of the product more dangerous than the ordinary consumer would expect;

c) Pinnacle Devices contained insufficient and/or incorrect warnings to alert consumers and users, including Plaintiff CARA A. BALDYGA of adverse effects and risks thereto;

d) Pinnacle Devices were not safe for its marketed use;

e) Pinnacle Devices were inadequately tested;

f) Pinnacle Devices were not accompanied by adequate instructions and/or warnings to fully apprise the implanting and/or prescribing physicians as well as the ultimate consumers, including the Plaintiff CARA A. BALDYGA, of the full nature or extent of the risks and side effects associated with its use.

129. Defendants knew and intended that the Pinnacle Devices would be purchased from Defendants by hospitals and orthopedic surgeons and would be used by such purchasers without any detailed inspection for defects and would rely upon the representations made by Defendants on the product label, in other promotional and sales materials and otherwise.

130. At the time of its manufacture and sale to Plaintiff, CARA A. BALDYGA, Pinnacle Devices were unsafe and defective to consumers using said product for its advertised purposes and in a reasonably foreseeable manner, in that it posed an unreasonably high risk of serious injury to consumers, which information was concealed by Defendants.

131. Prior to the manufacturing, sale and distribution of Pinnacle Devices, Defendants knew, or were reckless in not knowing, that said products were in a defective condition and that those who were implanted with said device were not at an unreasonable risk of experiencing injury. Further, Defendants through its officers, directors, and managing agents, had notice and knowledge from several sources, prior to the date of the marketing and sale of said Pinnacle Device to Plaintiff CARA A. BALDYGA, that the product presented potentially a substantial and unreasonable risk of harm to the consumer, including the Plaintiff, CARA A. BALDYGA, and as such, said consumers were unreasonably subjected to risk of injury from the use of that product.

132. Despite such knowledge, Defendants, through their officers, directors and managing agents, knowingly and deliberately failed to remedy the known defects in the Pinnacle Devices and failed to warn the public, including the Plaintiff CARA A. BALDYGA, of the serious risk of injury occasioned by the defects inherent in the product.

133. Upon information and belief, such failure to notify the public, including Plaintiff CARA A. BALDYGA, was for the purpose of increasing sales and enhancing their profits and Defendants intentionally proceeded with the manufacturing, sale and marketing of the Pinnacle Device knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests.

134. Plaintiff CARA A. BALDYGA used the medical device for its intended purpose.

135. Plaintiff CARA A. BALDYGA could not have discovered any defect in the Pinnacle Device or accompanying sales and promotional materials through exercise of due care.

136. Defendants as manufacturer, marketer, retailer, distributor, and seller of Pinnacle Devices are held to the level of knowledge of an expert in its field.

137. Plaintiff CARA A. BALDYGA did not have substantially the same knowledge as an adequate warning from defendants should have communicated.

138. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA was and/or still is caused to suffer and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, the need for additional surgery to repair, remove and/or replace the Pinnacle Device, as well as other severe and permanent health consequences.

139. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA requires and will require health care and services, and did incur medical, health,

incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

140. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(MANUFACTURING DEFECT)

141. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

142. Defendants' Pinnacle Device implanted in Plaintiff CARA A. BALDYGA had an impurity, imperfection, and/or another product defect allowed to be created, contained, or placed within the product in the manufacturing process.

143. This impurity, imperfection, and/or other product defect was a deviation from design and quality manufacturing standards.

144. As a result of the impurity, imperfection, and/or other product defect the Pinnacle Device was in a defective and unreasonably dangerous condition to Plaintiff CARA A. BALDYGA when it left Defendants' control.

145. Defendants knew or should have known that the Pinnacle Device would not be inspected for impurities, imperfections, and/or another product defects prior to its implantation into Plaintiff CARA A. BALDYGA, and that if it were inspected for such impurities,

imperfections, and/or another product defects by Plaintiff CARA A. BALDYGA or her healthcare providers, the same would not be discerned or perceived.

146. The Pinnacle Device was used in the manner intended.

147. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA was and/or still is caused to suffer and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, the need for additional surgery to repair, remove and/or replace the Pinnacle Device, as well as other severe and permanent health consequences.

148. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

149. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(FRAUD)

150. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

151. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution, and promotion of Pinnacle Devices, owed a duty to provide accurate and complete information regarding their use in Pinnacle Device surgeries.

152. Defendants through their literature, advertisements, promotions, and through representations by their marketing team and sales agents fraudulently misrepresented information regarding their Pinnacle Devices, including their propensity to cause serious and permanent physical harm by providing false, incomplete and misleading information.

153. Defendants made the aforesaid misrepresentations and actively concealed adverse information at a time when they knew or should have known that the products could cause permanent damage and concealed the fact that they did not do adequate testing.

154. At the time of Defendants' fraudulent misrepresentations and omissions, Plaintiff CARA A. BALDYGA and her healthcare providers were unaware of the falsity of the statements and reasonably relied upon defendants' deceptive, inaccurate and fraudulent misrepresentations in selecting the Pinnacle Device used in Plaintiff CARA A. BALDYGA's hip replacement surgery.

155. Defendants intentionally concealed the fact that the use of the Pinnacle Device in the manner in which they were marketed could cause permanent damage with the intent to defraud and mislead users and the medical community.

156. The concealments, misrepresentations, and false information communicated by Defendants were made with the intent to generate future profits to the significant detriment of the public and the Plaintiff CARA A. BALDYGA herein.

157. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA was and/or still is caused to suffer and/or is at a greatly increased risk of suffering

serious, dangerous side effects, including, but not limited to, severe pain and suffering, the need for additional surgery to repair, remove and/or replace the Pinnacle Device, as well as other severe and permanent health consequences.

158. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

159. By reason of the foregoing, Plaintiff CARA A. BALDYGA has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

160. Plaintiffs seek actual and punitive damages from Defendants as alleged herein

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

161. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

162. Defendants expressly warranted that the Pinnacle Device was safe and/or well accepted by users.

163. The Pinnacle Device does not conform to these express representations because the Pinnacle Device is not safe and has numerous serious risks and side effects. As a direct and proximate result of the breach of said warranties, Plaintiff CARA A. BALDYGA suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

164. Plaintiff CARA A. BALDYGA did rely on the express warranties of the Defendants herein.

165. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of the Pinnacle Device in total hip replacement surgeries.

166. The Defendants herein breached the aforesaid express warranties, as their Pinnacle Devices were defective.

167. Defendants expressly represented to the users, their physicians, healthcare providers, and/or the FDA that the Pinnacle Device was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

168. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the Pinnacle Device was not safe and fit for the use intended, and, in fact, produced serious injuries to the users.

169. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA was and/or still is caused to suffer and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, the need for additional surgery to repair, remove and/or replace the Pinnacle Device, as well as other severe and permanent health consequences.

170. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

171. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

172. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

173. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold the Pinnacle Device, which is used in total hip replacement surgeries.

174. At the time Defendants marketed, sold, and distributed the Pinnacle Device for use by Plaintiff CARA A. BALDYGA, Defendants knew of the use for which the Pinnacle Device was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

175. The Defendants impliedly represented and warranted to the users and their physicians, healthcare providers, and/or the FDA that the Pinnacle Device was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

176. That said representations and warranties aforementioned were false, misleading and inaccurate in that the Pinnacle Device was unsafe, unreasonably dangerous, improper, not of merchantable quality and defective.

177. Plaintiff CARA A. BALDYGA and members of the medical community did rely on said implied warranties of merchantability and/or fitness for a particular use and purpose.

178. Plaintiff CARA A. BALDYGA and her physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether the Pinnacle Device was of merchantable quality and safe and fit for its intended use.

179. The Pinnacle Device was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

180. The Defendants herein breached the aforesaid implied warranties, as their Pinnacle Devices were not fit for their intended purposes and uses.

181. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA was and/or still is caused to suffer and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, the need for additional surgery to repair, remove and/or replace the Pinnacle Device, as well as other severe and permanent health consequences.

182. As a result of the foregoing acts and omissions, the Plaintiff CARA A. BALDYGA requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff CARA A. BALDYGA is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

183. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(LOSS OF CONSORTIUM)

184. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

185. That on February 17, 2015 and at all times hereinafter mentioned, Plaintiff RALPH C. ACKROYD, was the lawful husband of Plaintiff CARA A. BALDYGA and they have cohabited together as such.

186. That by reason of the foregoing, the Plaintiff RALPH C. ACKROYD, was and remains deprived of the services, comfort, companionship, society and marital consortium of his wife CARA A. BALDYGA and has been physically, socially, and economically damaged as a result thereof.

187. That by reason of the foregoing, Plaintiff RALPH C. ACKROYD, has been damaged, in a sum of money exceeding the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this matter.

188. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

NINTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(PUNITIVE DAMAGES)

189. At all times material hereto, the Defendants knew or should have known that their Pinnacle Device was inherently more dangerous with respect to the risk of significant pain, irritation, discomfort and need for additional surgeries than the alternative hip arthroplasty systems on the market.

190. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

191. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiffs herein, concerning the safety and efficacy of the subject product.

192. At all times material hereto, the Defendants knew and recklessly disregarded the fact that the Pinnacle Device was subject to an increased risk of causing significant pain, irritation, discomfort and need for additional surgeries in persons implanted with the device with far greater frequency than safer alternative hip arthroplasty systems.

193. Notwithstanding the foregoing, the Defendants continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative methods.

194. The Defendants knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiffs herein, in conscious and/or negligent disregard of the foreseeable harm.

195. The Defendants' intentional and/or reckless, fraudulent and malicious failure to disclose information deprived the Plaintiff CARA A. BALDYGA and her surgeon of necessary information to enable them to weigh the true risks of using the subject product against its benefits.

196. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff CARA A. BALDYGA, the Plaintiff suffered severe and permanent physical injuries as set forth above.

197. The aforesaid conduct of defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

198. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

a. Awarding Plaintiff actual damages incidental to Plaintiff CARA A. BALDYGA's use of the Pinnacle Device in an amount to be determined at trial;

b. Awarding treble and/or punitive damages to Plaintiffs;

c. Awarding pre-judgment and post-judgment interest to Plaintiffs;

d. Awarding the costs and expenses of this litigation to Plaintiffs;

e. Awarding reasonable attorneys' fees and costs to Plaintiffs as provided by law; and

f. Granting all such other, further and/or different relief as the Court may deem just and proper.

Dated: July 3, 2018

By: /s/ Thomas J. Schiro

Thomas J. Schiro
BELLUCK & FOX, LLP
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New York, New York 10036
T-(212) 681-1575
F-(212) 681-1574
Attorneys for Plaintiffs CARA A. BALDYGA and RALPH C. ACKROYD

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury on all issues so triable.

Dated: July 3, 2018

By: /s/ Thomas J. Schiro

Thomas J. Schiro
BELLUCK & FOX, LLP
546 Fifth Avenue, 4th Floor
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Attorneys for Plaintiffs
CARA A. BALDYGA and RALPH C. ACKROYD

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

CARA A. BALDYGA and RALPH C. ACKROYD

(b) County of Residence of First Listed Plaintiff Pinellas
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Belluck & Fox, LLP. 546 5th Avenue, 4th Floor, NY NY 10036
212-681-1575
Thomas Schiro, Esq.

DEFENDANTS

DEPUY ORTHOPARDICS, INC. and JOHNSON & JOHNSON

County of Residence of First Listed Defendant Kosciusko
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. Section 1332
Brief description of cause:

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Ed Kinkeade DOCKET NUMBER 3:11-MD-2244

DATE 07/03/2018

SIGNATURE OF ATTORNEY OF RECORD s/Thomas Schiro

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE